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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/405,269 09/23/99 ALBERTE

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IM52/0925

EXAMINER

YAMNITZKY, M

ART UNIT	PAPER NUMBER
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1774

DATE MAILED:

09/25/01

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/405,269	Applicant(s) Randall S. ALBERTE et al.
Examiner M. Yamnitzky	Art Unit 1774



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three (3) MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 14, 2001

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-88 is/are pending in the application.

4a) Of the above, claim(s) 27, 28, 34-37, and 75-88 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-26, 29-33, and 38-74 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 67ed

20) Other: 05/02/00 and 11/09/00

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1. Applicants' election without traverse of Group I, claims 1-74, in Paper No. 11 (received 05/14/01) is acknowledged.

Applicants' election without traverse of the species of compound of general structure 1, applied to the surface of a medical device, wherein X represents -OH, Y represents O and Z represents optionally substituted aryl is also acknowledged.

Claims 1-26, 29-33 and 38-74 read on the elected species.

2. Claims 75-88 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 11.
3. Claims 27, 28 and 34-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to non-elected species. Election was made **without** traverse in Paper No. 11. Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.
4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

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An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

5. The use of various trademarks such as Teflon®, Dacron®, Gore-tex® and Marlex® have been noted in this application (e.g. page 38, line 29 and p. 40, l. 29). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. Claim 64 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to describe how to make a “permanent” coating comprising an effective amount of anti-fouling compound represented by general structure 1 wherein the coating releases the compound when in contact with a surface of an article selected from grafts, implants and medical devices. As the compound is released from the coating, the content of the compound of general structure 1 in the coating will decrease until such time as there is no more compound of general structure 1 in the coating, and the coating comprising the compound of general structure

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1 no longer exists. It is unknown how such a coating could ever be made to be a "permanent" coating.

7. Claims 5, 12, 13, 17, 21, 22, 43, 50, 51, 55, 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although compounds within the scope of these claims are named in the specification, there are no examples demonstrating that any compounds within the scope of these claims are anti-fouling compounds. The only compounds for which data of anti-fouling capabilities is presented are zosteric acid, octyl sulfate and methyl sulfate. None of these three compounds meets the limitations of claims 5, 12, 13, 17, 21, 22, 43, 50, 51, 55, 59 and 60.

8. Claims 1-26, 29-33 and 38-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependents are drawn to a system comprising a surface comprising a compound represented by general structure 1, but the last line of claim 1 recites "the compound is released from the surface". The last line of claim 1 confuses the scope of these claims because it is not clear if the compound is actually part of the surface of the claimed system. Alternatively, if

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this language is intended to indicate that the compound is part of the surface but can be released from the surface, then “is released” should be changed to --is releasable-- or --can be released-- or other appropriate language.

Claim 29 is confusing. It is not clear how a decrease in the amount of plant pathogens attached to a plant or plant component is relevant to a system adapted for use in a health-related environment. It is not clear if the system must be or must comprise a plant or plant component.

Claim 29 is also rendered indefinite by the recitation of “a defined period of time” with no limitation on the defined period of time.

Claim 31: The basis for the percents is not known. That is, are the percents by weight, volume or moles; and is the percent of compound measured relative to biofilm resistant surface, the system, or some other measure?

Claim 39 and dependents: It is not clear if these claims are drawn to a coating, *per se*, or to the combination of a coating and a graft, implant or medical device, wherein the coating is applied to a surface of the graft, implant or medical device.

Claim 64: It is not clear how a coating comprising a compound of general structure 1, wherein the compound can be released from the coating when in contact with the surface of a graft, implant or medical device, can be permanent. If the compound is released, over time, the coating will cease to comprise the compound of general structure 1. When no more compound of general structure 1 is present, a coating comprising a compound of general structure 1 no longer exists.

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Claim 65 is confusing. It is not clear how a decrease in the amount of plant pathogens attached to a plant or plant component is relevant to a coating applied to a surface of a graft, implant or medical device. It is not clear if the graft, implant or medical device must be or must comprise a plant or plant component.

Claim 65 is also rendered indefinite by the recitation of “a defined period of time” with no limitation on the defined period of time.

Claim 67: The basis for the percents is not known. That is, are the percents by weight, volume or moles; and is the percent of compound measured relative to biofilm resistant surface, the system, or some other measure?

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-4, 7-11, 16, 19, 20, 25, 26, 29-33, 38-42, 45-49, 54, 57, 58, 63 and 65-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmerman et al. (5,384,176).

Glass microscope slides coated with various phenolic acid sulfate esters are disclosed by Zimmerman et al. Each of the compounds disclosed by Zimmerman et al. meets the limitations of

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a compound represented by general structure 1 wherein X represents -OH, Y represents O, and Z represents a substituted aryl. See the whole patent. In particular, see Fig. 1A, 1B, 1C, column 2, line 47 - c. 3, l. 26 and c. 4, l. 59 - c. 5, l. 10.

Given the extremely broad definition of "health-related environment" (see page 17 of the present specification), the coated microscope slides disclosed by Zimmerman et al. meet the limitations of a system as claimed in present claim 1 and dependents. Microscope slides find use in a health-related environment such as a medical diagnostic laboratory.

Microscope slides are also considered by the examiner to meet the limitations of a medical device.

With respect to claims 71-73, if claim 39 and dependents are drawn to a coated graft, implant or medical device rather than to a coating, *per se*, the coated microscope slides of Zimmerman et al. are considered by the examiner to at least meet the limitations of claim 73 since "can be applied" does not require any particular time period or mode of application.

With respect to claim 39 and dependents, even if microscope slide are to be considered outside the scope of a medical device, the coating compositions used to coat the glass microscope slides in Zimmerman's examples meet the limitations of a coating, *per se*. If the claimed subject matter is the coating, *per se*, then application to a surface of a graft, implant or medical device merely indicates the intended use of the coating.

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Claims 7 and 45 are included in this rejection because while these claims further limit R, these claims are not limited to a compound of general structure 1 comprising R. R is present only in the case where Y represents NR, and these claims do not require Y to represent NR.

Claims 29 and 65 are included in this rejection given that these claims do not limit the “predefined” period of time, do not limit the specific plant pathogen(s) to be reduced, and because the prior art compounds are within the scope of the compounds represented by general structure

1. It is reasonable to expect that the coatings containing phenolic acid sulfate esters that are disclosed in the prior art and are within the scope of the compound required by the present claims are capable of reducing at least some plant pathogens by a factor of 4 relative to a control over some unlimited period of time.

11. Claims 39-42, 44-49, 52-54, 56-58, 61-63, 65 and 69-73 are rejected under 35 U.S.C. 102(a) or 102(b) as being anticipated by applicants’ admissions in the present specification.

This rejection is applicable if claim 39 and dependents are drawn to a coating, *per se*. If these claims are drawn to a coating, *per se*, application of the coating to a surface of a graft, implant or medical device merely indicates the intended use of the coating.

Octyl sulfate and methyl sulfate are known compounds. As admitted in the specification, octyl sulfate has extensive industrial applications and is manufactured by several large chemical companies (p. 47, l. 6-7). A solution of octyl sulfate in water was available from Stepan Chemical

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Co. prior to the filing date of the present application as admitted by applicant (p. 47, l. 12). If the solution of octyl sulfate in water was available from Stepan Chemical Co. more than one year prior to the filing date of the present application, the present claims reading on a liquid coating comprising octyl sulfate are rejected under 35 U.S.C. 102(b). If the solution of octyl sulfate in water was available from Stepan Chemical Co. less than one year prior to the filing date of the present application, the present claims reading on a liquid coating comprising octyl sulfate are rejected under 35 U.S.C. 102(a).

Further, any solution of octyl sulfate or methyl sulfate that was commercially available prior to the filing date of the present invention, and any disclosure in a printed publication of such a solution prior to the filing date of the present invention, anticipates a liquid coating comprising the sulfate under 35 U.S.C. 102(b) or 35 U.S.C. 102(a), depending upon whether the availability and/or printed disclosure occurred more than or less than one year prior to the filing date of the present application.

12. Miscellaneous:

Each of claims 27, 33, and 63 is lacking a period at the end of the claim.

Claim 70 contains two periods at the end of the claim.

13. The prior art made of record and not relied upon is considered pertinent to applicants' disclosure.

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Each of the patents to Shepherd et al. (3,632,416), Galin (4,240,163) and Chesterfield et al. (5,312,642) discloses medical devices coated with sulfate compounds. For example, see Examples 2, 8 and 9 in the Shepherd patent, see column 2, lines 3-18 and the claims in the Galin patent, and see column 7, line 60 - c. 8, l. 9 in the Chesterfield patent.

14. Any inquiry concerning this communication should be directed to Marie R. Yamnitzky at telephone number (703) 308-4413. The examiner can generally be reached at this number from 6:45 a.m. to 3:15 p.m. Monday-Friday.

The current fax numbers for Art Unit 1774 are (703) 305-3599 for official after final faxes and (703) 305-5408 for all other official faxes. (Unofficial faxes to be sent directly to examiner Yamnitzky can be sent to (703) 872-9041.)

MRY
09/24/01

Marie R. Yamnitzky

MARIE YAMNITZKY
PRIMARY EXAMINER

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